

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

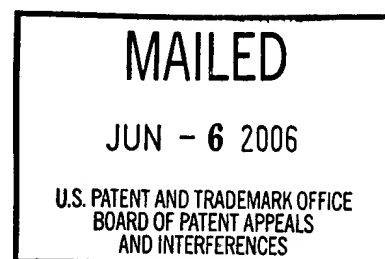
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte CLEMENTS C. LAMBETH and
NICHOLAS C. WHEELER

Appeal No. 2006-0138
Application No. 09/618,307

ON BRIEF



Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a tree breeding method, which the examiner has rejected as lacking adequate description, nonenabled, and obvious. We have jurisdiction under 35 U.S.C. § 134. We reverse the rejections for lack of adequate description and nonenablement, but affirm the rejection for obviousness.

Background

"For decades, tree breeders have faced the dilemma of how to mate a select group of individuals (parents) for the next generation of genetic improvement." Specification, page 1. "[T]he type of plant breeding strategy selected for use in a plant breeding program depends upon a number of different factors. However, a common

goal of a plant breeding program is to generally use a breeding method that will result in the largest possible genetic gain using the smallest number of breeding crosses and the least amount of time and money.” Page 7.

“Mating designs that have been commonly compared in the literature are open pollination versus controlled pollination and, for the latter, full-sib crossing versus polymix (a mixture of pollen from several males) crossing.” Id. “Polymix crossing is done by mixing pollen from several males and applying the pollen to isolated females. One of the advantages to polymix crossing is the simplicity of crossing and subsequent testing of relatively few crosses.” Page 5.

“PMX [polymix] crossing provides excellent estimation of breeding value and general combining ability (GCA) but not usually specific combining ability (SCA). . . . Genetic gain potential for forward selection is good but not as high as that offered by the commonly used full-sib systems.” Page 6. “The primary reason that PMX systems result in less genetic gain from advanced generation selections versus full-sib systems is due to the fact that the paternal parent’s GCA is unknown.” Id.

The specification discloses “a plant breeding design which utilizes PMX crosses in conjunction with molecular marker technology to determine pedigree. Given a sufficient number of reliable, polymorphic molecular markers, and modest care in creation of pollen polymixes, paternity of all PMX progeny can be unambiguously determined through molecular analysis. Therefore, the [disclosed method] provides a plant breeding method that allows for pedigree control and estimation of breeding values of the parental plants and their progeny.” Page 8.

Discussion

1. Claim construction

Claims 20-31 are pending and on appeal. The claims stand or fall together because Appellants have not argued them separately. See 37 CFR § 41.37(c)(1)(vii).

We will focus on claim 20, the only independent claim, which reads as follows:

20. A tree breeding method comprising:

(a) mixing pollen obtained from a breeding group comprising a plurality of parental trees to obtain a pollen polymix;

(b) pollinating female reproductive structures from each parental tree in the plurality of parental trees with the pollen polymix to obtain a plurality of progeny lots, wherein each progeny lot comprises seeds obtained from a different cross between the pollen polymix and each different parental tree of the plurality of parental trees;

(c) evaluating progeny trees grown from each of the progeny lots using objective criteria to obtain a phenotype score;

(d) determining the pedigree of a plurality of progeny trees using DNA analysis; and

(e) using the pedigree and phenotype score to identify elite trees for use in a next generation of tree breeding.

Thus, claim 20 is directed to a method comprising (1) mixing pollen from a group of male parental trees, (2) pollinating female parental trees with the pollen polymix, (3) evaluating the resulting progeny trees “using objective criteria to obtain a phenotype score,” (4) “determining the pedigree of a plurality of progeny trees using DNA analysis,” and (5) using the combined phenotype score and pedigree information to choose which progeny trees to use in the next round of breeding.

2. Written description

The examiner rejected claims 20-31 under 35 U.S.C. § 112, first paragraph, on the basis that the specification did not adequately describe the claimed method. The examiner reasoned that the claims “are broadly drawn to a method of using a multitude of non-exemplified DNA markers from a multitude of taxonomically unrelated and physiologically and genetically divergent tree species.” Examiner’s Answer, page 4.

The examiner found that the specification did not provide a description of corresponding breadth: “[T]he specification only provides guidance for SSRs [simple sequence repeats; specification, page 9] from a single coniferous species, Pinus taeda. No guidance is provided for the isolation or characterization of any other type of DNA marker from any tree species.” Id., page 6. The examiner concluded that “[g]iven the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described.” Id., page 7.

Appellants summarize their position as follows: “Claims 20-31 are supported by an adequate written description because (a) the art of tree breeding, including the use of polymix crosses, was mature at the time the application was filed; (b) the art of DNA analysis to distinguish individual trees was mature at the time the application was filed; (c) no knowledge of DNA sequence is necessary to practice the methods of the invention; and (d) the methods of the invention do not require a correlation between a desirable trait of a plant and a DNA sequence.” Appeal Brief, page 9.

"[The written description] inquiry is a factual one and must be assessed on a case-by-case basis." Purdue Pharma L.P. v. Faulding, Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000). The specification need not describe the invention in the same terms used in the claims, but the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. See id.

The degree of specificity required to adequately describe an invention "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). See also id. at 1359, 76 USPQ2d at 1085: "[W]hat is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter."

In this case, we agree with Appellants that the examiner has not adequately explained why a skilled worker in the field of tree breeding would have found the present specification inadequate to show possession of the claimed method. The evidence of record supports Appellants' position that persons working in the field of tree breeding knew how to use DNA markers to determine the pedigree of different trees. See, e.g., Stoehr,¹ page 188: "DNA markers represent powerful and useful genetic markers for seed orchard management research. Especially useful for this purpose are

¹ Stoehr et al., "Application of a chloroplast DNA marker in seed orchard management evaluations of Douglas-fir," Can. J. For. Res., Vol. 28, pp. 187-195 (1998)

markers that are associated with the chloroplast, which is paternally inherited in Douglas-fir . . . , providing a direct determination of male parentage.” In addition, the specification cites numerous prior art references that are said to describe the use of DNA markers in tree breeding. See pages 15-16 and 18-20.

Since the evidence of record shows that those skilled in the art were familiar with the use of DNA markers to determine paternity in tree breeding research, we agree with Appellants that those skilled in the art would not have considered a description of specific DNA markers to be necessary in order to show possession of the claimed method. The rejection for lack of adequate written description is reversed.

3. Enablement

The examiner also rejected claims 20-31 under 35 U.S.C. § 112, first paragraph, on the basis that practicing the claimed method would have required undue experimentation. The examiner argued that “[p]olymix-mediated breeding of trees for phenotypic change is unpredictable, given the lack of available knowledge regarding flower biology or pollination control in many tree species.” Examiner’s Answer, page 11. “Furthermore, the use of polymix breeding may be confounded by the unequal reproductive success of many parents’ pollen. . . . The claimed method relies upon the assumption of equal reproductive success for its determination of pedigree and its selection of elite trees for future breeding programs.” Id., pages 12-13. The examiner cited Wiseloge² as evidence that the Pinus taeda exemplified in the specification is “unique regarding equal reproductive success of various parents’ pollen.” Id., page 13.

² Wiseloge et al., “Probability of equal mating in polymix pollinations of loblolly pine (*Pinus taeda* L.),” Silvae Genetica, Vol. 37, pp. 184-187 (1988)

Finally, the examiner argued that “molecular marker-mediated selection in tree breeding . . . is unpredictable,” and concluded that undue experimentation would have been required to practice the full scope of the claimed method. Id., page 14.

Appellants argue that the amount of experimentation involved in practicing the claimed method is not undue (Appeal Brief, pages 19-33), that the claimed method does not require an assumption of equal reproductive success (Reply Brief, pages 1-2), and that the claimed method does not involve marker-assisted selection (Appeal Brief, pages 16-18).

We agree with Appellants that the examiner has not adequately explained why the claimed method would require undue experimentation. The examiner’s first point – that plant breeding involving polymix crosses is unpredictable – relates to plant breeding in general, or at any rate to plant breeding designs involving polymix crosses. Yet the evidence of record shows that polymix mating designs are commonly used in the field of tree breeding. See Bridgwater,³ page 72 (Mating designs involving polymix crosses, or polycrosses, are “in general usage.”). It therefore appears that those of skill in the art of tree breeding consider the degree of unpredictability involved in polymix crosses to be within the expected amount of experimentation.

With regard to the other two specific points made by the examiner – that the claimed method relies on an assumption of equal reproductive success and that molecular marker-mediated selection in tree breeding is unpredictable – we agree with Appellants that these factors have no relevance to the claimed method. Appellants

³ Bridgwater, “Mating Designs,” in Fins et al. (eds.), Handbook of Quantitative Forest Genetics, pp. 69-95 (1992)

argue, and we agree, that the claimed method does not rely on an assumption of equal reproductive success. No such assumption is needed because the method involves a step of determining, via DNA analysis, the paternity of the selected elite progeny prior to using them in the next round of breeding. Because the paternity of the selected progeny are determined based on DNA analysis, there is no need to assume that each of the male parental trees was equally likely to be the male parent of a given progeny plant.

Nor does the claimed method rely on molecular marker-mediated selection. The examiner cites Strauss⁴ as evidence that “molecular markers are of limited availability and of high cost, are restricted to particular genetic backgrounds, and that many traits of interest to tree breeders are highly environmentally influenced, which would interfere with selection of phenotypes to which markers could be reliably assigned.” Examiner’s Answer, page 14.

However, the methods discussed by Strauss are not required to practice the method claimed in this case. Strauss relates to linkage of quantitative trait loci (QTL) with genetic markers:

By QTL we refer to polymorphic loci containing alleles that differentially affect the expression of a continuously distributed phenotypic trait such as height. Such loci are rarely observed directly, but are instead inferred to exist via the correlation of linked genetic markers with phenotypic trait values. By genetic markers we refer to effectively neutral, nuclear genome markers, usually RFLPs.

Page 1051, right-hand column.

⁴ Strauss et al., “Limitations of molecular-marker-aided selection in forest tree breeding,” Can. J. For. Res., Vol. 22, pp. 1050-1061 (1992)

That is, the molecular marker-aided selection discussed by Strauss is a method of selecting plants having QTL associated with a desired trait by screening for a marker, such as an RFLP, that is linked to the desirable QTL. In the claimed process, by contrast, the phenotypes of the progeny trees can be analyzed by any "objective criteria," which "include[s] the measurement of any plant characteristic or phenotype with any detection/measurement device that provides statistically meaningful data regarding the characteristic or phenotype being measured." Specification, page 10. We agree with Appellants that the claimed method does not require molecular marker-assisted selection. Therefore, the degree of unpredictability or amount of experimentation required to practice molecular marker-assisted selection is not a factor in the enablement analysis of the claimed method.

We conclude that the examiner has not adequately explained why practicing the claimed method would have required undue experimentation. We therefore reverse the rejection for nonenablement.

4. Obviousness

The examiner also rejected claims 20-31 under 35 U.S.C. § 103 as obvious in view of Bridgwater, El-Kassaby,⁵ and Stoehr. He reasoned that Bridgwater teaches the general method of tree breeding using a pollen polymix, but "does not teach the use of molecular markers to determine pedigree." Examiner's Answer, pages 20-21. The examiner relied on El-Kassaby for its teaching of using isozyme testing "to determine

⁵ El-Kassaby et al., "Frequency-dependent male reproductive success in a polycross of Douglas fir," Theor. Appl. Genet., Vol. 83, pp. 752-758 (1992)

the pedigree of progeny from a polymix cross of Douglas fir trees,” and Stoehr’s “use of DNA markers to identify pedigree in Douglas fir.” Id., page 21.

The examiner also pointed out that Stoehr teaches that DNA markers provide advantages over isozymes when determining pedigree; in particular, using markers found in chloroplast DNA “provid[es] a direct determination of male parentage,” because chloroplasts are paternally inherited. The examiner concluded that it would have been obvious in view of the combined references to modify the polymix breeding method taught by Bridgwater by adding a step of analyzing the pedigree of progeny trees, as taught by El-Kassaby, using DNA markers such as those taught by Stoehr. See the Examiner’s Answer, page 22.

We agree with the examiner that the cited references would have made the method of claim 20 obvious to those of skill in the art. Bridgwater teaches that polymix mating (or polycross mating) is a “mating design[] in general usage that do[es] not provide information on male pedigrees, rather only the female pedigree is known.” Page 72. Bridgwater teaches that a polycross mating “[p]rovides for good estimates of gca [general combining ability] effects” (page 74) and provides for good estimates of gains that arise from additive genetic variation (id.). Bridgwater also teaches that using a polymix is less expensive than controlled-cross mating: “[T]he number of crosses required to accomplish the objectives of polycross matings is usually several times smaller than the numbers required for controlled-cross mating designs” (page 76).

However, Bridgwater teaches that polycross matings have disadvantages compared to controlled crosses. First, “no estimate of sca [specific combining ability] effects are possible since the male parents are unknown.” Page 74. Second, polycross

mating “[d]oes not provide for control of male pedigrees if a single polymix is used on all parents.” Page 75. The lack of control over male pedigree can reduce the expected gains because a few of the male parents can produce most of the progeny. See id. Thus, Bridgwater teaches that polymix mating designs have many advantages – cost, in particular – but suffer from the drawback that the plant breeder does not know the male pedigree of the selected progeny.

El-Kassaby teaches a method of determining the male pedigree in progeny of polymix crosses. El-Kassaby used male parental plants that expressed different sets of alleles for four enzymes;⁶ i.e., the combination of the four alleles was different for each of the male parents. See Table 1. El-Kassaby then carried out a polymix mating and analyzed the enzyme alleles present in the progeny (page 753, right-hand column, first two paragraphs). El-Kassaby used the enzyme alleles in the progeny to determine which of the male parents was the parent of each progeny seed. See Table 2.

Stoehr teaches a method of paternity analysis based on chloroplast DNA markers. Stoehr teaches that analysis of chloroplast DNA “provid[es] a direct determination of male parentage,” because “the chloroplast . . . is paternally inherited in Douglas-fir.” Page 188, left-hand column, second paragraph. Stoehr exemplifies the analysis of pedigree based on chloroplast markers in a “supplemental mass pollination” technique.⁷ Based on the DNA-based analysis of male pedigree, Stoehr concluded that “[o]utside-orchard contamination was reduced roughly by half . . . in clones treated with SMP compared with controls.” Paragraph bridging pages 191 and 192.

⁶ Different alleles of enzymes are also known as isozymes. See, e.g., El-Kassaby, Table 1.

⁷ “Supplemental mass pollination (SMP), or the broadcast of viable pollen to nonisolated receptive strobili, is a common crop-management practice in conifer seed orchards.” El-Kassaby, page 758.

We agree with the examiner that these teachings support a prima facie case of obviousness. Bridgwater teaches that polymix crosses are useful but suffer limitations because the male pedigree is unknown. El-Kassaby teaches a method for determining the male pedigree of the progeny of a polymix cross. Stoehr teaches that determining male pedigree via DNA analysis has advantages over the isozyme analysis used by El-Kassaby.

Therefore, it would have been obvious to a person of ordinary skill in the art to improve the polymix method taught by Bridgwater by adding a step of determining the male pedigree of the progeny, as taught by El-Kassaby, in order to solve the known limitations that arise from not knowing the male pedigree of polymix progeny. It would also have been obvious to determine male pedigree using DNA analysis, because Stoehr teaches the advantages of using chloroplast DNA markers to analyze male pedigree. Finally, it would have been obvious to the skilled tree breeder to consider both phenotype data and male pedigree data in choosing which progeny to use in the next round of breeding, because doing so would overcome the disadvantages discussed by Bridgwater.

Appellants argue that none of the references individually teach or suggests all of the steps of claim 20. See the Appeal Brief, pages 36-37. Appellants also argue that none of the references teach or suggest step (e) of claim 20: using phenotype and pedigree analysis together to choose which trees to use in the next round of breeding. Id., pages 37-38.

These arguments are not persuasive. "Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a

combination of references.” In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test for obviousness is what the combined teachings of the references as a whole would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Considered as a whole, the references would have suggested all of the steps of claim 20, including step (e), for the reasons discussed above.

Appellants also argue that “Bridgwater teaches away from the use of polymix breeding by stating that ‘[i]f there is strong variation for general combining ability among males and inbreeding depression is present, selection in base populations produced from polycross matings will reduced expected gains since most selections may be progenies of the same few pollen parents.’” Appeal Brief, page 36.

This argument is also unpersuasive. Bridgwater teaches that polymix breeding is commonly used and has several advantages but also has limitations, including the one discussed in the quoted passage, that arise from not knowing the male pedigree of progeny. However, a person of ordinary skill in the art, familiar with the references relied on by the examiner, would have realized that determining the male pedigree of the progeny of a polymix cross would remedy the known problems of polymix mating designs. Therefore, we do not agree with Appellants’ argument that Bridgwater would have led away from a polymix-based breeding method.

Summary

We reverse the rejections for lack of adequate written description and nonenablement. However, we agree with the examiner that the prior art would have suggested the method of claim 20 to a person of ordinary skill in the art. Claims 21-31

fall with claim 20. We therefore affirm the rejection of claims 20-31 under 35 U.S.C.
§ 103.

No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED



Toni R. Scheiner
Administrative Patent Judge



Demetra J. Mills
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge

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